Transmittal Letter to the United States Designated/Elected Office (DO/EO/US)

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Docket No. : LZ-48PCT

U.S. Application No. :

International Application No.: PCT/EP99/07540

International Filing Date: October 7, 1999 (7. Oktober 1999)

Priority Date Claimed: October 9, 1998 (9. Oktober 1998)

Title of Invention: DEVICE FOR CARRYING OUT MEDICAL INTERVENTIONS AND A METHOD FOR GENERATING AN IMAGE

Applicant(s) for (DO/EO/US): Dorothee Auer & Ludwig M. Auer

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. X This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ___ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. X This express request to begin national examination procedures 35 U.S.C. 371 (f) at any time rather than delay examination until the expiration of the applicable time limit set forth in 35 U.S.C 371(b) and PCT Articles 22 and 39(1).
4. ___ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. X A copy of the International Application as filed [35 U.S.C. 371(c)(2)].
   a) X is transmitted herewith (required only if not transmitted by the International Bureau)
   b) ___ has been transmitted by the international Bureau.
   c) ___ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ___ A translation of the International Application into English [35 U.S.C.371(c)(2)].
7. ___ Amendments to the claims of the International Application under PCT Article 19 [35 U.S C 371(c)(3)].
   a) ___ are transmitted herewith (required only if not transmitted by the International Bureau)
   b) ___ have been transmitted by the International Bureau.
   c) ___ have not been made; however, the time limit for making such amendments has **NOT** expired.
   d) ___ have not been made and will not be made.
8. ___ A translation of the amendments to the claims under PCT Article 19 [35 U.S.C.371(c)(3)].
9. ___ An oath or declaration of the inventor(s) [35 U.S.C.371(c)(4)].
10. ___ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 [35 U.S C.371(c)(5)]

Items 11. to 16. below concern other document(s) or information included:

11. ___ An Information Disclosure Statement under 37 C.F.R. 1.97 and 198.
12. ___ An Assignment document for recording. A separate cover sheet in compliance with 37 CFR 3 28 and 3.31 is included.
13. ___ A **FIRST** preliminary amendment.
    ___ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ___ A substitute specification
15. ___ A change of power of attorney and/or address letter.
16. X (other items or information) **Five sheets of drawings**

EXPRESS MAIL No.: **EL 670 216 040 US** Deposited: **April 9, 2001**

I hereby certify that this correspondence is being deposited with the United States Postal Service Express mail under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, DC 20231.

Barbara Ernzerhoff-Snow

April 9, 2001
Date

17. X The following fees are submitted:

	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE [37 CFR 1.492(a)(1)-(5)]:		
X Search Report has been prepared by the EPO or JPO..... $ 860.00		
___ International preliminary examination fee paid to USPTO [37 CFR 1 482]:..... $ 690.00		
___ No International preliminary examination fee paid to USPTO [37 CFR 1.482] but International search fee paid to USPTO [37CFR 1.445(a)(2):..... $ 710.00		
___ Neither International preliminary examination fee [37 CFR 1.482] nor International search fee [37 CFR 1.445(a)(2)]) paid to USPTO:..... $1,000.00		
___ International preliminary examination fee paid to USPTO [37 CFR 1.482] and all claims satisfied provisions of PCT Article 33 (2) to (4):..... $ 100.00		
ENTER APPROPRIATE BASIC FEE AMOUNT:	$ 860.00	
Surcharge of $ 130.00 for furnishing the oath or declaration later than ___20 ___30 months from the earliest claimed priority date [37 CFR 1.492(e)]	$ 860.00	
Claims filed Extra Rate		
Total Claims 18 -20= x $ 18.=	$	
Indep. Claims 2 - 3= x $ 78.=	$	
Multiple Dependent Claims (if applicable) + $ 260.=	$	
TOTAL OF ABOVE CALCULATIONS:	$ 860.00	
Reduction by ½ for filing by small entity, if applicable. Verified Small Entity Statement must be filed also. [Note 37 CFR 1.9,1.27, 1.28] (divided by 2)	$ 430.00	
SUBTOTAL:	$ 430.00	
Processing fee of $ 130.00 for furnishing the English Translation later than ___20 ___30 months from the earliest claimed priority date [37 CFR 1.492(f)]	$	
TOTAL NATIONAL FEE:	$ 430.00	
Fee for recording the enclosed assignment [37 CFR 1.21(h)] The assignment must be accompanied by an appropriate cover sheet [37 CFR 3.28,3.31]. $ 40.00 per property	$	
TOTAL FEES ENCLOSED:	$ 430.00	
AMOUNT TO BE REFUNDED:	Refunded	$
AMOUNT TO BE CHARGED:	Charged	$

a) X A check in the amount of **$ 430.00** to cover the above fees is enclosed.

b) _ Please charge my Deposit Account No. 11-1835 in the amount of $ to cover the above fees
A duplicate copy of this sheet is enclosed.

c) X The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **11-1835**. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 36 CFR 1.494 or 1.495 has not been met, a petition to revive [37 CFR 1.137(a) or (b)] must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO: Friedrich Kueffner
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Friedrich Kueffner Friedrich Kueffner /fe 29,482 April 9, 2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

LZ-48PCT

Applicant : Ludwig M. Auer

Serial No. : 09/807,164

Int. Filed : October 7, 1999

For : DEVICE FOR CARRYING OUT MEDICAL INTERVENTIONS AND A METHOD FOR GENERATING AN IMAGE

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

S I R:

In advance of the first office action, please amend the claims as follows:

IN THE CLAIMS

Replace current claims 1 - 12 and 14 - 18 by the enclosed amended claims 1 - 12 and 14 - 18. A marked-up version of amended claims 1 - 12 and 14 - 18 is also enclosed.

REMARKS

Claims 1 - 18 are in the application.

As a result of the foregoing amendment, the claims have been amended to remove improper multiple dependencies.

Any additional fees or charges required at this time in connection with the application may be charged to our Patent and Trademark Office Deposit Account No. 11-1835.

Respectfully submitted,

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July 3, 2001
FK:ml
ENCLS:
Amended Claims;
Marked-Up Version.

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July 3, 2001 Friedrich Kueffner

AMENDED CLAIMS

1. Device for performing medical interventions (operations) on the human or animal body, with

a device (18) for storing first image data in regard to the area to be operated on and

a device (22) for displaying image data,

wherein

an image-generating device (20) for obtaining second image data of the area to be operated on during the operation, and

an updating device (10, 12), which is configured to compare second image data obtained at a first point in time to second image data obtained at a second point in time that is after the first point in time, to update the first image data, in accordance with the changes resulting from the comparison, and to supply the updated first image data to the display device (22).

2. Device according to claim 1, wherein the updating device (10, 12) updates the first image data at predetermined time intervals.

3. Device according to claim 1, wherein the updating device (10, 12) updates the first image data always when the changes resulting from the comparison surpass a predetermined limit.

4. Device according to claim 1, wherein a surgical robot (24) which is configured to carry out manually input commands while taking into account the updated first image data and/or to perform automatically at least one operation step according to a predetermined program.

5. Device according to claim 4, wherein the surgical robot (24) is configured to work within a limited preset volume in the area to be operated on and represented by the updated first image data.

6. Device according to claim 4, wherein the surgical robot (24) is configured to maintain a predetermined distance to a predetermined boundary surface in the area to be operated on and represented by the updated first image data.

7. Device according to claim 4, wherein the surgical robot (24) is configured to move to a predetermined point within the area to be operated on and represented by the updated first image data.

8. Device according to claim 4, wherein a device for inputting the limitation volume, the boundary surface, and/or the target point.

9. Device according to claim 1, wherein a calibration device (14) which can be fixedly mounted on the body and which has at least one landmark which, with respect to the body provides a fixed, common reference point for the first and the second image data.

10. Device according to claim 9, wherein the calibration device (14) is formed by a stereotactic frame.

11. Device according to claim 1, wherein the first image data have been obtained by way of computer tomography and/or magnetic resonance imaging.

12. Device according to claim 1, wherein the image-generating device (20) works by ultrasound for obtaining second image data.

13. Method for generating an image of a human or animal body, comprising the following steps:

- storing first image data of the body;

- acquiring second image data of the body at a first and at a second point in time, the second point in time being after the first point in time;

- comparing the second image data, recorded at the first point in

time and the second point in time, with one another;

- updating the first image data corresponding to the change resulting from the comparison; and

- displaying the updated first image data.

14. Method according to claim 13, wherein the first point in time and the position of the body during acquiring of the second image data are selected such that the second image data acquired at the first point in time correspond to the stored first image data.

15. Method according to claim 13, wherein the step of updating is performed in predetermined time intervals.

16. Method according to claim 13, wherein the step of updating is performed every time when the changes resulting from the comparison surpass a predetermined limit.

17. Method according to claim 13, wherein the first image data have been obtained by way of computer tomography or magnetic resonance imaging.

18. Method according to claim 13, wherein the second image data are recorded by means of ultrasound.

MARKED-UP VERSION OF AMENDED CLAIMS

1. Device for performing medical interventions (operations) on the human or animal body, with

a device (18) for storing first image data in regard to the area to be operated on and

a device (22) for displaying image data,

[characterized by] wherein

an image-generating device (20) for obtaining second image data of the area to be operated on during the operation, and

an updating device (10, 12), which is configured to compare second image data obtained at a first point in time to second image data obtained at a second point in time that is after the first point in time, to update the first image data, in accordance with the changes resulting from the comparison, and to supply the updated first image data to the display device (22).

2. Device according to claim 1, [characterized in that] wherein the updating device (10, 12) updates the first image data at predetermined time intervals.

3. Device according to claim 1, [characterized in that] wherein the updating device (10, 12) updates the first image data always when the changes resulting from the comparison surpass a predetermined limit.

4. Device according to [one of the preceding claims, characterized by] claim 1, wherein a surgical robot (24) which is configured to carry out manually input commands while taking into account the updated first image data and/or to perform automatically at least one operation step according to a predetermined program.

5. Device according to claim 4, [characterized in that] wherein the surgical robot (24) is configured to work within a limited preset volume in the area to be operated on and represented by the updated first image data.

6. Device according to [claim 4 or 5, characterized in that] claim 4, wherein the surgical robot (24) is configured to maintain a predetermined distance to a predetermined boundary surface in the area to be operated on and represented by the updated first image data.

7. Device according to [one of the claims 4 to 6, characterized in that] claim 4, wherein the surgical robot (24) is configured to move to a predetermined point within the area to be operated on and represented by the updated first image data.

8. Device according to [one of the claims 4 to 7, characterized by' claim 4, wherein a device for inputting the limitation volume, the boundary surface, and/or the target point.

9. Device according to [one of the preceding claims, characterized by] claim 1, wherein a calibration device (14) which can be fixedly mounted on the body and which has at least one landmark which, with respect to the body provides a fixed, common reference point for the first and the second image data.

10. Device according to claim 9, [characterized in that] wherein the calibration device (14) is formed by a stereotactic frame.

11. Device according to [one of the preceding claims, characterized in that] claim 1, wherein the first image data have been obtained by way of computer tomography and/or magnetic resonance imaging.

12. Device according to [one of the preceding claims, characterized in that] claim 1, wherein the image-generating device (20) works by ultrasound for obtaining second image data.

13. Method for generating an image of a human or animal body, comprising the following steps:

- storing first image data of the body;

- acquiring second image data of the body at a first and at a second point in time, the second point in time being after the first point in time;

- comparing the second image data, recorded at the first point in time and the second point in time, with one another;

- updating the first image data corresponding to the change resulting from the comparison; and

- displaying the updated first image data.

14. Method according to claim 13, [characterized in that] wherein the first point in time and the position of the body during acquiring of the second image data are selected such that the second image data acquired at the first point in time correspond to the stored first image data.

15. Method according to [claim 13 or 14, characterized in that] claim 13, wherein the step of updating is performed in predetermined time intervals.

16. Method according to [claim 13 or 14, characterized in that] claim 13, wherein the step of updating is performed every time when the changes resulting from the comparison surpass a predetermined limit.

17. Method according to [one of the claims 13 to 16, characterized in that] claim 13, wherein the first image data have been obtained by way of computer tomography or magnetic resonance imaging.

18. Method according to [one of the claims 13 to 17, characterized in that] claim 13, wherein the second image data are recorded by means of ultrasound.

2001

Translation of WO 00/21450 (PCT/EP99/07540)

Device for Carrying Out Medical Interventions and a Method for Generating an Image

The invention relates to a device for carrying out medical interventions (operations) on the human or animal body, comprising a device for storing first image data of the area to be operated on which are, for example, obtained by means of computer tomography and/or magnetic resonance imaging, and comprising a device for displaying image data.

In contrast to operations in the orthopedic field, the area to be operated on, for example, in brain surgery and liver surgery, will change during the intervention. In the case of, for example, coagulation of a brain tumor there are actually two effects.

The brain tumor, on the one hand, will drop, and, on the other hand, will decrease its volume, wherein the brain will fill out immediately the volume that has been freed by the coagulating tumor. Accordingly, it is required to intraoperatively update pre-operatively obtained image data in order to prevent that, as a result of false or missing information in regard to the actual position of the tumor to be coagulated, damage will be caused to the adjoining brain.

In order to obtain detailed information in regard to the area to be operated on, image-providing methods are used which are, for example, magnetic resonance imaging and computer tomography. Both image-generating methods are suitable only to a limited extent, or

not at all, for intraoperative image generation. Image-generating methods by means of ultrasound can be used intraoperatively, but the image data obtained therewith are usually not detailed enough.

It is therefore an object of the invention to provide a device of the aforementioned kind with which, intraoperatively, sufficiently detailed image data can be obtained and displayed.

According to the invention the above object is solved for a device of the aforementioned kind by an image-generating device, which, for example, operates with ultrasound, for obtaining second image data of the area to be operated on during the operation and an updating device which is configured to compare second image data, obtained at a first point in time, with second image data, obtained at a second point in time that is after the first point in time, and to update the first image data according to the change resulting from the comparison, and to supply the updated first image data to the display device.

In other words, image data, which cannot be obtained or obtained only with difficulty intraoperatively, are however obtained preoperatively with sufficient detail and can be updated and displayed intraoperatively by means of image data which can be obtained more easily but with less detail during operation so that an updated and sufficiently detailed, even though artificially generated, image is obtained and displayed. Accordingly, according to the invention the image data obtained intraoperatively are not themselves displayed but are only used to update substantially more detailed image data obtained preoperatively.

Methods for updating image data are generally known in medical technology, for example, from the following publications:

"Individualizing Anatomical Atlases of the Head" in "Visualization in Biomedical Computing", 1996; "Medical Image Segmentation Using Topologically Adaptable Surfaces", in "CVRMed-MRCAS '97", March 1997, pp. 23-32; "Segmentation Using Deformable Models with Affinity-Based Localization", in "CVRMed-MRCAS '97", March 1997, pp. 54-62; "Volumetric Medical Images Segmentation Using Shape Constrained Deformable Models", in "CVRMed-MRCAS '97", March 1997, pp. 13-22; "Shape-Based Segmentation and Tracking in 4D Cardiac MR Images", in "CVRMed-MRCAS '97", March 1997, pp. 43-52; "Decimation of Iso-Surfaces with Deformable Models", in "CVRMed-MRCAS '97", March 1997, pp. 84-92.

According to the invention it can be preferably provided that the updating device updates the first image data in certain time intervals. The time intervals are adjusted in this context to the specific requirements of the operation to be performed. Some changes, such as, for example, shrinkage in connection with coagulation, require that updating is performed essentially in real time. This can mean many updates per second.

However, it may also be provided that the updating device updates the first image data every time when the changes resulting from the comparison surpass a certain limit. In other words, an update is carried out only when this is required because changes that have to be considered have occurred. In this way, the computing time and computing capacity required for the update can be reduced to a minimum.

Preferably, the device according to the invention has a surgical robot which is configured to carry out, taking into account the updated first image data, manually input commands and/or to automatically perform at least one operation step according to a

predetermined program. In other words, the surgical robot works automatically based on the respectively updated first image data and/or it is guided by a surgeon who can take the respectively updated image data from the display device and who has optionally direct visual contact with the area to be operated on by means of endoscopic devices.

According to the invention it can be provided that the surgical robot is configured to work within the limits of a predetermined volume within the area to be operated on and represented by the updated first image data. This volume can be, for example, a brain tumor to be coagulated. Accordingly, the surgical robot in this case is limited to the coagulation of the tumor so that the adjoining brain substance is not endangered.

According to the invention, the surgical robot be configured to maintain a predetermined spacing to a predetermined boundary surface in the area to be operated on and represented by the updated first image data. In this connection it holds true also that the brain substance bordering the area to be operated on is protected against damage by the surgical robot.

Moreover, according to the invention, the surgical robot can be configured to move to a predetermined point in the area to be operated on and represented by the updated first image data. Such a target point can be, for example, the center of a brain tumor to be coagulated.

According to the invention, it is preferred to provide a device for inputting the limit volume, the boundary surface and/or the target point. By doing so, the surgeon has the possibility to set preoperatively and/or intraoperatively the limits for the surgical

robot required for safety and described above or to define a target point which is to be reached by the surgical robot at the beginning, during the course, or at the end of the operation.

According to the invention, it is preferred to provide a calibrating device which is to be arranged fixedly on the body and which has at least one landmark which, relative to the body, represents a fixed common reference point for the first and the second image data. Such a calibrating device serves, for example, for enabling adjusting, directly before the beginning of the operation, image data, obtained by ultrasound, with image data obtained preoperatively by way of computer tomography or by magnetic resonance imaging by means of so-called co-registration.

The calibrating device, according to the invention, is preferably formed by a stereotactic frame. Of course, other (equivalent) devices can be used for this purpose.

The invention concerns moreover a method for generating an image of the human or animal body.

As has been mentioned above, there are situations, for example, during an operation, in which only such image generating methods can be used which provide insufficiently detailed image data.

The invention also concerns the object to provide a method of the aforementioned kind which provides intraoperatively detailed image data even when a correspondingly detailed image generating method cannot be used intraoperatively.

According to the invention, the above object is solved by a method with the following steps:

- storing first image data of the body obtained, for example, by means of computer tomography or magnetic resonance imaging,

- recording second image data of the body, for example, by means of ultrasound, at a first point in time and a second point in time which is after the first point in time;

- comparing with one another the second image data recorded at the first and the second points in time;

- updating the first image data according to the change resulting from the comparison; and

- displaying the updated first image data.

As has been mentioned above in detail with reference to the device according to the invention, according to the method of the invention in certain situations, i.e., for example, during an operation, an image generating method is used which provides less detailed image data, wherein it is not these less detailed image data but the detailed image data updated based on the change of the less detailed image data that are displayed.

It is expressly stated that the method according to the invention relates exclusively to the generation or display of an image of the human or animal body and not to a diagnostic method or therapy. For a diagnostic method it is indeed required not only to generate and display the image but also to evaluate it. For a therapy, measures on the body are required which surpass the pure generation and the pure display.

According to the invention, the first point in time and the position of the body are selected upon recording of the second image data such that the second image data taken at the first point in time correspond to the stored first image data.

In other words, a calibration is performed inasmuch as the first and the second image data are adjusted once relative to one another in that they represent one and the same state of the body.

According to the invention, the step of updating can be performed in predetermined time intervals.

However, it can also be provided that the step of updating is performed (only) when the changes resulting from the comparison surpass a predetermined limit. This makes it possible to save computing time and computing capacity.

In the following, the invention is explained in more detail with the aid of preferred embodiments with further details with reference to the attached drawing, wherein the drawing

> shows schematically an embodiment of the device according to the invention.

The core piece of the device according to the invention is a computer 10 with a comparator 12. By means of a stereotactic frame 14 fixedly connected on the body, for example, connected to the head for neurosurgical purposes, a computer tomogram and/or a magnetic resonance image is recorded preoperatively, with consideration of landmarks, by means of a computer tomographic or a magnetic resonance imaging device 16. The obtained image data are then stored in a memory 18. At the beginning of the operation,

by using the same stereotactic frame 14, an ultrasound image is recorded by means of an ultrasound device 20 which is then adjusted for calibration purposes by means of the computer tomogram or the magnetic resonance image.

The preoperatively obtained computer tomogram or magnetic resonance image is displayed by means of the display, for example, in the form of a monitor 22.

During the course of the operation, which is performed, for example, by means of a surgical robot 24, ultrasound images are produced again and again which are compared with the preceding ultrasound images. The deviations which are obtained thereby serve for changing the computer tomogram or the magnetic image accordingly. The most recent version of the computer tomogram or the magnetic resonance image which has been updated accordingly is supplied, on the one hand, from the computer 12 to the monitor 22 so that the surgeon is informed continuously about the course of the operation. On the other hand, it is also used in order to control the surgical robot 24, wherein this includes, for example, that it is being input with a volume to be operated (changing during the course of the operation), wherein it is furthermore also programmed to maintain a predetermined spacing from a boundary surface previously input into the computer.

The surgical robot 24, inter alia, is capable of the following:

- automatic limitation to a space defined by the surgeon;

- automatically maintaining a predetermined spacing to a surface in the area operated and/or,

- return to a preselected point in the area to be operated on or along the operative access path.

Programming of this robotic performance is realized in that the surgeon provides manually limit values on slice images of pre-operatively obtained image data sets which then result in points, distances or spaces and can be used for the control of the surgical robot 24. Such a point can be a starting or target point or a return point on an operative access path. A distance can be a connecting line between different points on an access path to an area to be operated on or within the area to be operated on. A space or volume can be the periphery of a solid or cystic tumor or a cyst or its wall whose outer boundary is not to be touched by a surgical instrument.

For controlling the spatial conditions and their changes during an operation, the surgeon uses the intraoperative ultrasound imaging.

Before the operation, a 3-D data set is generated with an image-forming method such as magnetic resonance imaging or computer tomography. This data set serves as a reference image for the further steps. During this examination, the stereotactic frame 14 is fastened on the head of the patient for neurosurgical purposes. This frame 14 contains landmarks which can be used for calibration or co-registration of the systems at the beginning of the operation. At the point of beginning the operation, the surgical robot 24, which is, for example, in the form of a robot arm, is brought into a fixed predetermined spatial relation to the mounted stereotactic frame 14 and is fixedly mounted. Subsequently, the landmark points are traced with the tip of the operating instrument functioning as the calibration device so that an unequivocal relation between the working space of the robot and the space of

the preoperatively produced images is generated. A similar fixed correlation is then generated between the stereotactic frame 14 and the ultrasound head 20 to be implanted for generating three-dimensional ultrasound images. With this fixed predetermined correlation between the preoperative image space and the intraoperative ultrasound image space there is the possibility to initially simply determine changes in the area to be operated on by means of ultrasound imaging.

Subsequently, a so-called co-registration between the preoperative and the intraoperative images is carried out with the goal to transfer this information in real time to the robot arm and to thus adjust the planned operation steps to the momentary spatial conditions. Moreover, this co-registration step makes it possible to maintain a respective qualitatively highest display of the momentary conditions with regard to the image representation, which serves as an orientation for the surgeon during the intervention, in that by means of the co-registration, for example, the preoperative 3-D magnetic resonance data set is adjusted and displayed according to the spatial changes recognized intraoperatively by the ultrasound image. The co-registered changed magnetic resonance data set as an artificial product of a co-registration step will thus produce images which have an appearance as if, intraoperatively, magnetic resonance imaging had been performed. In reality, however, the image information of the intraoperative ultrasound imaging has been used to alter the preoperative magnetic resonance data set such that the new magnetic resonance image corresponds to the actual spatial conditions and is identical to the actual ultrasound image. In this way, image details of the magnetic resonance image, which cannot be shown in the ultrasound image, can optionally also be shown in this modified form that is adjusted to the momentary situation so that the

surgeon is presented with a high resolution virtual image of the area to be operated on. On the other hand, it is also possible to represent image contents which do not occur in the pre-operative image, i.e., which are obtainable only by means of ultrasound.

In detail, this co-registration mechanism means that the pre-planned target points, distances, surfaces, and spaces of the robot space are adjusted respectively to the momentary conditions within the area to be operated on. They make possible an updated precise operation.

This means that, for example, when a coagulation probe is activated in order to coagulate the central area of a tumor, the entire tumor will shrink as a result of the coagulation process and the tumor boundaries preset pre-operatively by the surgeon no longer correspond to the actual tumor boundaries. The device according to the invention is able to observe and to document the movements of these preset boundaries, i.e., to register the volume changes and to transmit these to the surgical robot. The volume which has been predetermined during preoperative planning by the surgeon is referred to as the "alarm volume". The control software for registration of changes of this volume or changes of the surface of this volume is referred to as the "alarm volume adaptation tool" (AVAT).

One of the programs for surgical robot performance is designed to coagulate automatically a volume pre-planned by the surgeon. In this context, the automatic coagulation process is stopped as soon as the momentarily coagulated volume has reached at one location the planned volume. In this connection, the performance of the AVAT must be taken into account which ensures that the planned volume toward the end of the coagulation process no longer

corresponds to the momentary volume because the entire tumor during the coagulation process has shrunk. The coagulation process is thus adapted according to the movement of the tumor surface during the coagulation process and terminated earlier.

The next operation step is then comprised of, for example, moving the tip of the coagulation probe into the center of that new sphere which contains the greatest possible residual tumor proportion to be coagulated next. In this connection, the AVAT must be taken into account again between planned and momentary volume. Moreover, for this and the subsequent steps for the third, fourth etc. coagulation, the movement of the probe tip is guided from the momentary position to a predetermined entry point and from there along an access path to the new target point.

A further program course is, for example, provided in order to scan the inner surface of a cystic tumor with a surgical instrument, to first coagulate a predetermined layer thickness and to then scrape off the coagulated tissue. In this context, the distance maintenance program is activated which ensures that a safety distance is maintained relative to the coagulation boundary so that bleeding is prevented during the tumor removal.

The features of the invention disclosed in the above description, the claims as well as the drawing can be important individually as well as in any chosen combination for the realization of the invention in its different embodiments.

Claims

1. Device for performing medical interventions (operations) on the human or animal body, with

a device (18) for storing first image data in regard to the area to be operated on and

a device (22) for displaying image data,

characterized by

an image-generating device (20) for obtaining second image data of the area to be operated on during the operation, and

an updating device (10, 12), which is configured to compare second image data obtained at a first point in time to second image data obtained at a second point in time that is after the first point in time, to update the first image data, in accordance with the changes resulting from the comparison, and to supply the updated first image data to the display device (22).

2. Device according to claim 1, characterized in that the updating device (10, 12) updates the first image data at predetermined time intervals.

3. Device according to claim 1, characterized in that the updating device (10, 12) updates the first image data always when the changes resulting from the comparison surpass a predetermined limit.

4. Device according to one of the preceding claims, characterized by a surgical robot (24) which is configured to carry out manually input commands while taking into account the updated first image data and/or to perform automatically at least one operation step according to a predetermined program.

5. Device according to claim 4, characterized in that the surgical robot (24) is configured to work within a limited preset volume in the area to be operated on and represented by the updated first image data.

6. Device according to claim 4 or 5, characterized in that the surgical robot (24) is configured to maintain a predetermined distance to a predetermined boundary surface in the area to be operated on and represented by the updated first image data.

7. Device according to one of the claims 4 to 6, characterized in that the surgical robot (24) is configured to move to a predetermined point within the area to be operated on and represented by the updated first image data.

8. Device according to one of the claims 4 to 7, characterized by a device for inputting the limitation volume, the boundary surface, and/or the target point.

9. Device according to one of the preceding claims, characterized by a calibration device (14) which can be fixedly mounted on the body and which has at least one landmark which, with respect to the body provides a fixed, common reference point for the first and the second image data.

10. Device according to claim 9, characterized in that the calibration device (14) is formed by a stereotactic frame.

11. Device according to one of the preceding claims, characterized in that the first image data have been obtained by way of computer tomography and/or magnetic resonance imaging.

12. Device according to one of the preceding claims, characterized in that the image-generating device (20) works by ultrasound for obtaining second image data.

13. Method for generating an image of a human or animal body, comprising the following steps:

- storing first image data of the body;

- acquiring second image data of the body at a first and at a second point in time, the second point in time being after the first point in time;

- comparing the second image data, recorded at the first point in time and the second point in time, with one another;

- updating the first image data corresponding to the change resulting from the comparison; and

- displaying the updated first image data.

14. Method according to claim 13, characterized in that the first point in time and the position of the body during acquiring of the second image data are selected such that the second image data

acquired at the first point in time correspond to the stored first image data.

15. Method according to claim 13 or 14, characterized in that the step of updating is performed in predetermined time intervals.

16. Method according to claim 13 or 14, characterized in that the step of updating is performed every time when the changes resulting from the comparison surpass a predetermined limit.

17. Method according to one of the claims 13 to 16, characterized in that the first image data have been obtained by way of computer tomography or magnetic resonance imaging.

18. Method according to one of the claims 13 to 17, characterized in that the second image data are recorded by means of ultrasound.

Abstract

The invention concerns a device for carrying out medical interventions on the human or animal body as well as a method for generating an image of the human or animal body.

According to the invention, first image data obtained pre-operatively are updated by means of second image data obtained intraoperatively, in particular, updated corresponding to the changes between two second image data recorded at different points in time.

COMBINED DECLARATION FOR PARENT APPLICATION AND POWER OF ATTORNEY
(includes Reference to PCT International Applications)

Attorney's Docket No. LZ-48

As a below named inventor, I hereby declare that:
My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: DEVICE FOR CARRYING OUT MEDICAL INTERVENTIONS AND A METHOD FOR GENERATING AN IMAGE

the specification of which (check only one item below):

[ ] is attached hereto.

[ ] was filed as United States application
Serial No. _____,
on _____
and was amended
on _____ (if applicable).

[X] was filed as PCT international application
Number PCT/EP99/07540,
on October 7, 1999
and was amended under PCT Article 19
on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT, indicate PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
GERMANY	198 46 687.0	9 October 1998	[X] YES [ ] NO
			[ ] YES [ ] NO

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Combined Declaration For Parent Application and Power of Attorney (Continued) *(includes Reference to PCT International Applications)*	Docket No. LZ-48

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of the application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty of disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occured between the filing date of the prior application(s) and the national or PCT internation filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (CHECK ONE)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED

PCT APPLICATIONS DESIGNATING THE U.S.					
PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NO.			

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(List name and registration number)*

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Combined Declaration For Parent Application and Power of Attorney (Continued) *(includes Reference to PCT International Applications)*	Docket No. LZ-48

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE OF INVENTOR 201	*SIGNATURE OF INVENTOR 202*	*SIGNATURE OF INVENTOR 203*
DATE 3.7.01	*DATE*	*DATE*

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